Minutes
Registration Review Workgroup
Pesticide Program Dialogue Committee
August 11, 2003 Teleconference

Participants:

EPA:	Betty Shackleford, Richard Dumas, Michael Nieves, Philip Ross, Tim Kiely, Teresa Downs, Ingrid Sunzenauer, and Vivian Prunier
Work Group Members:	Britt Bailey, Cindy Baker, Steve Kellner, Therese Murtagh, Steve Rutz, Julie Spagnoli, Roberta Spitko, Janine Rynczak (substituting for Warren Stickle), and Ray McAllister

Minutes of July 16 Meeting. In addition to editorial changes, the date of the next face-to-face meeting was corrected. The meeting will be held on October 28, the day before the PPDC meeting and not on October 16 as announced at the meeting and stated in the draft minutes. It was agreed that the October 16 date would be reserved for a teleconference if necessary.

Criteria for Scheduling Registration Review. The workgroup participants agreed with the finding in the draft paper that the most logical basis for scheduling registration review was the date of the initial registration or the reregistration eligibility decision. Participants said that they needed a predictable schedule and an orderly process. Workgroup members agreed to revise the paper in time for the next teleconference.

Scope of Registration Review. EPA asked the Workgroup to clarify its suggestion that registration review does not include inert ingredients. FIFRA section 3(g) states that the registrations of pesticides shall be periodically reviewed. Pesticide registrations include all the ingredients in a pesticide – active and inert. Accordingly, the Agency believes that registration review must account for inert ingredients. The Agency is trying to develop approaches to accomplish the review of all pesticide registrations, including inert ingredients, and asks the Workgroup's help on this issue.

What is a Registration Review Decision? All participants agreed that the purpose of a registration review was to determine whether a pesticide meets the requirements of FIFRA section 3(c)(5). Among other things, FIFRA section 3(c)(5) specifies that use of the pesticide will not cause unreasonable adverse effects on the environment. Under the definition of "unreasonable adverse effects" in FIFRA section 2(bb), EPA must consider, among other things, whether human dietary exposures to a pesticide meet the safety standard established in section 408 of the Federal Food, Drug and Cosmetic Act.

The participants discussed whether the Agency could conclude that a pesticide's registration met the requirements of FIFRA section 3(c)(5) if additional data are necessary for a

registration review. The Agency reminded the Workgroup that FIFRA section 3(g)(2)(A) states that the Agency shall require submission of data that are necessary for a registration review. EPA interprets this provision to mean that the registration review cannot be completed until examination of the new data deemed necessary for a registration review shows that the pesticide continues to meet the requirements of FIFRA section 3(c)(5).

Workgroup members proposed that a registration review could find that a pesticide registration was in compliance with FIFRA requirements, including any requirement to submit data necessary for a registration review, and suggested that a decision as to whether the pesticide meets the requirements of FIFRA section 3(c)(5) could be postponed until the data have been submitted and examined. EPA agreed that under some circumstances, a registration review decision could acknowledge pending data that were called in under a special data call-in. The review of these data could be separate from the registration review of the pesticide.

Workgroup members suggested that EPA call in studies as soon as the Agency recognizes a need for data on a chemical or on a group of chemicals that share common attributes. This way the studies would be available for the pesticide's registration review and the review could be completed on schedule.

Workgroup members suggested that registration review should not include a DCI for data requirements that have not been codified in Part 158 of 40 CFR. Such requests for data should be made in special DCI projects. EPA acknowledged that it might be difficult for registrants to prepare for a registration review when there is uncertainty about what information will be needed to support continued registration of the pesticide. If the Agency finds that additional data are necessary for the registration review, it would require submission of such data, even if the data requirement has not been codified in 40 CFR Part 158.

Deciding on the Level of Assessment. EPA asked the workgroup to consider ways in which the registration review process could avoid the "one-size-fits-all" approach that the Agency used in the reregistration program.

Workgroup members suggested that the Agency ask three questions to gauge the level of assessment: 1) have requirements changed since the last review? 2) has anything new happened, e.g., new uses, new hazard information, new alternatives 3) have risk assessment methods or policy changed since the last review? If the answer to all these questions is "no," the registration review would be essentially complete. If the answer to one or more of these questions is "yes," the Agency should consult with stakeholders to see whether the risk assessment should be refined or if risk mitigation measures should be considered.

Betty asked the Workgroup to consider additional criteria for assessing the level of assessment and suggested that members review OPP's proposed approach for registration review (i.e., the material presented to the PPDC in April).

Action Items

- EPA to send meeting notes to workgroup members within a week.
- Workgroup members to revise the "Scope" paper and the "Scheduling Criteria" paper before the next meeting.
- EPA to clarify its position on the inclusion of inert ingredients in registration review (completed; see page 1, paragraph 3 of these meeting notes).
- EPA to provide a list of active ingredients that shows the date of the last major action.
- Cindy Baker, Julie Spagnoli, Therese Murtagh and Steve Kellner will draft a paper on "deciding the level of assessment" by September 12.

Agenda for September 24 Teleconference

- Complete discussion of "deciding levels of assessment."
- Begin discussion of stakeholder involvement in the registration review process.